CASE STUDY

REDX

SHAININ STRATEGIES ACHIEVE BLOOD TEST KIT FIELD REPRODUCIBILITY SUCCESS

A global manufacturer of products used for diagnosis of infectious diseases was seeking FDA 510(k) clearance for a new test kit. The new kit can rapidly test for multiple strains of a highly contagious disease from a variety of culture types.

THE PROBLEM

Although their internal testing had shown that they had met the strict FDA requirements for test kit sensitivity, they had failed to replicate the results in the field during various clinic and hospital trials. Without knowing whether the difference was caused by one of the many steps in the testing process or the different types of measurement equipment at each site, they were not able to implement the appropriate changes or controls. Assumed differences or educated guesses ran the risk of failing the next round of field testing. This would lead to an unnecessary test expense as well as a delay in FDA clearance, thus delaying the introduction of the product to the market.

THE APPROACH

The manufacturer and Shainin established a project team and set out to identify which specific step in the process was driving the difference between the successful in-house testing and the unsuccessful field testing. By using a technique called Operations Search and creating special test batches at each site, large portions of the test process were eliminated. In a short period of time, with minimal samples and tests, the team was able to isolate the specific step and procedure driving the differences in sensitivity.

With this new knowledge, the team was able to implement the appropriate changes to sample preparation and meet the FDA sensitivity requirements.

BENEFITS

1. Field trials now matched the stellar performance of in-house testing.
2. Variability in batch sensitivity was significantly reduced.

SHAININ